

OCT 11 1996

Gallini

K962905

Summary of Safety and Effectiveness

Owner : Gallini s.r.l.
88. Via S. Faustino
41037-Mirandola -Italy

Contact Person: Caterina E. Galluzzo
President, Gallini Intl.

Submission Date: July 1996

Device Name : TX® Biopsy Needle

Predicate Device : Promedical Ltd.. - PRO-B Biopsy Needle (510 (k) # K951598)

Description of Device function : This device is an automatic disposable biopsy Needle developed for taking a range of tissue specimens, including those from the prostate, kidney and liver.

Intended Use : This device is an automated, disposable and adjustable biopsy instrument designed for ultimate accuracy in obtaining high quality histological core samples, with three different choice of penetration depth and obtaining histological samples from 0.8 to 1.9 mm length.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The TX® Biopsy Needle is equivalent to the predicate devices in term of technological characteristics

The following tests was performed to show the safety, efficacy and performance of the product.

TEST	RESULT
Gun Firing Test (TX/F/T) see attch. protocol	passed
Pyrogen Test (LAL)	passed
All biocompatibility tests on the components are performed by the supplier of the raw material.	